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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/804,360

03/19/2004

Roger Farnholtz

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EXAMINER

BHATIA, AARTI

ART UNIT

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3763

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/804,360	Applicant(s) FARNHOLTZ, ROGER	
	Examiner Aarti Bhatia	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2008 and 02 October 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-22, 24-26, 28-35, 37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-22, 24-26, 28-35, 37 and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 3/19/2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the fourth Office Action based on the 10/804,360 application filed on 3/19/2004.

Claims 19-22, 24-26, 28-35, and 37-38, as amended on 8/13/2008, are currently pending and have been considered below.

Response to Amendment

The amendment to the claims filed on 8/13/2008 does not comply with the requirements of 37 CFR 1.121(c) because claims 32 and 33 are marked as “currently amended”, however the word “junction” had previously been removed from the claims in the amendment dated 4/25/2008. Amendments to the claims filed on or after July 30, 2003 must comply with 37 CFR 1.121(c) which states:

(c) *Claims*. Amendments to a claim must be made by rewriting the entire claim with all changes (e.g., additions and deletions) as indicated in this subsection, except when the claim is being canceled. Each amendment document that includes a change to an existing claim, cancellation of an existing claim or addition of a new claim, must include a complete listing of all claims ever presented, including the text of all pending and withdrawn claims, in the application. The claim listing, including the text of the claims, in the amendment document will serve to replace all prior versions of the claims, in the application. In the claim listing, the status of every claim must be indicated after its claim number by using one of the following identifiers in a parenthetical expression: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New), and (Not entered).

(1) *Claim listing*. All of the claims presented in a claim listing shall be presented in ascending numerical order. Consecutive claims having the same status of “canceled” or “not entered” may be aggregated into one statement (e.g., Claims 1–5 (canceled)). The claim listing shall commence on a separate sheet of the amendment document and the sheet(s) that contain the text of any part of the claims shall not contain any other part of the amendment.

(2) *When claim text with markings is required*. All claims being currently amended in an amendment paper shall be presented in the claim listing, indicate a status of “currently amended,” and be submitted with markings to indicate the changes that have been made relative to the immediate prior version of the claims. The text of

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any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. Only claims having the status of “currently amended,” or “withdrawn” if also being amended, shall include markings. If a withdrawn claim is currently amended, its status in the claim listing may be identified as “withdrawn—currently amended.”

(3) *When claim text in clean version is required.* The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, *i.e.*, without any markings in the presentation of text. The presentation of a clean version of any claim having the status of “original,” “withdrawn” or “previously presented” will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of “withdrawn” or “previously presented.” Any claim added by amendment must be indicated with the status of “new” and presented in clean version, *i.e.*, without any underlining.

(4) *When claim text shall not be presented; canceling a claim.*

(i) No claim text shall be presented for any claim in the claim listing with the status of “canceled” or “not entered.”

(ii) Cancellation of a claim shall be effected by an instruction to cancel a particular claim number. Identifying the status of a claim in the claim listing as “canceled” will constitute an instruction to cancel the claim.

(5) *Reinstatement of previously canceled claim.* A claim which was previously canceled may be reinstated only by adding the claim as a “new” claim with a new claim number.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the overlap between the braid and the tubular shaft must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate

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prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 19-22, 24-26, 28-35 and 37-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 19, 28, and 37 contain the phrase "wherein the braid overlaps the distal end of the tubular shaft". The

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specification at page 5, merely describes the relation of the braid and the tubular shaft as attached at a junction. There is no mention of whether the braid lays over or under the tubular shaft.

Claim Rejections - 35 USC § 102 and 103

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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7. Claims 19, 20, 21, 22, 24, 26, 28, 29, 30, 31, 32, 33, 35, 37, and 38 rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over U.S. Patent No 5,228,441 to Lundquist.

8. Lundquist discloses the following:

19. A medical device, comprising: a proximal shaft section (31) and a distal shaft section extending distally of the proximal shaft section; the proximal shaft section includes a tubular proximal shaft section having a proximal end (32) and a distal end (33); a plurality of slits defined in the proximal tubular shaft section ; wherein a greater number of slits are disposed near the distal end of the proximal tubular shaft section than near the proximal end of the proximal tubular shaft section (column 4, lines 20-37); a distal shaft section (54) attached to the proximal shaft section, the distal shaft section including a braid attached to the distal end of the proximal tubular shaft section; wherein the braid overlaps the distal end of the tubular shaft such that a portion of the braid is located proximal of the distal end of the tubular shaft (see figure 3); and a polymer layer (46) disposed over the proximal and distal shaft sections tubular shaft and the braid (column 4, lines 38-40).

20. The medical device of claim 19, wherein the distal shaft section is deflectable (column 5, lines 33-36).

21. The medical device of claim 19, wherein proximal shaft section the tubular shaft has a longitudinal axis and wherein the slits are arranged generally perpendicular to the longitudinal axis (see figure 4).

22. The medical device of claim 19, wherein the medical device has a transition in stiffness from the proximal shaft section to the distal shaft section (it is inherent that the stiffness of a slotted tube and a braided member are different since they constructed differently).

24. The medical device of claim 19, wherein the number of slits per unit length is greater near the distal end of the tubular shaft than near the proximal end of the tubular shaft (column 4, lines 20-37).

26. The medical device of claim 19, wherein the tubular shaft is a nickel-titanium alloy tube (column 9, lines 47-51).

28. A medical device, comprising: a proximal shaft portion (31) and a distal shaft portion (54); the proximal shaft portion including a tubular member having a proximal end (32) and a distal end (33), the tubular member including a plurality of slits (41) defined in the tubular member; the distal shaft portion including a braid (54), the braid attached to the tubular member and extending distally therefrom (column 5, lines 12-24); wherein the braid overlaps the distal end of the tubular member such that a portion of the braid is located proximal of the distal end of the tubular member (see figure 3); and a polymer layer (46) disposed over the tubular member and the braid (column 4, lines 38-40).

29. The medical device of claim 28, wherein the distal shaft portion is deflectable (column 5, lines 33-36).

30. The medical device of claim 28, wherein the tubular member has a longitudinal axis and wherein the slits are arranged generally perpendicular to the longitudinal axis (see figure 4).

31. The medical device of claim 28, wherein the medical device has a transition in stiffness from the proximal shaft portion to the distal shaft portion (it is inherent that the stiffness of a slotted tube and a braided member are different since they constructed differently).

32. The medical device of claim 28, wherein a greater number of slits are disposed near the distal end of the tubular member than near the proximal end of the tubular member (column 4, lines 20-27).

33. The medical device of claim 28, wherein the number of slits per unit length is greater near the distal end of the tubular member than near the proximal end of the tubular member (column 4, lines 20-27).

35. The medical device of claim 28, wherein the tubular member is a nickel-titanium alloy tube (column 9, lines 47-51).

37. A medical device, comprising: a slotted tubular member (31) having a plurality of slots (41) therein, the slotted tubular member having a proximal end (32), a distal end (33), and a longitudinal axis; wherein the slots vary in number, location, frequency, size, or depth so that the tubular member varies in stiffness between the proximal end and the distal end (column 4, lines 20-37); a braid (54) attached to the distal end of the tubular member and extending distally therefrom (column 5, lines 12-24); wherein the braid overlaps the distal end of the tubular member such that a portion

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of the braid is located proximal of the distal end of the tubular member (see figure 3); and a polymer layer (46) disposed over the tubular member and the braid so as to define a catheter shaft (column 4, lines 38-40).

38. The medical device of claim 37, wherein the slots defined are arranged generally perpendicular to the longitudinal axis (see figure 4).

As the Applicant has discussed, the term “overlap” can have two interpretations.

Under the definition “to have an area or range in common with”, the above claims are clearly anticipated by Lundquist as set forth above.

Under the definition “to lie or extend over and cover part of”, the above claims are found to be obvious over Lundquist, as it would have been obvious to one having ordinary skill in the art at the time the invention was made to rearrange the braid to overlies the tubular member, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

9. Claims 25 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lundquist in view of U.S. Patent No. 5,437,288 to Schwartz.

Lundquist discloses the medical device of claims 19 and 28, and teaches that there can be variation in the number, frequency, and location of slits (column 4, lines 20-37) but fails to disclose wherein the depth of slits is greater near the distal end/junction of the proximal shaft section than near the proximal end/junction of the proximal shaft section.

Schwartz teaches a flexible catheter (figure 2), where the depth of slits (14) becomes greater when moving from the proximal end (11) to the distal end (12) (column 4, lines 5-8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the flexible catheter of Lundquist with the variable depth slits of Schwartz because by increasing the depth of the grooves, the flexibility of the flexible portion nearest the distal end is increased (column 4, lines 8-11).

Response to Arguments

10. Applicant's arguments filed 8/13/2008 and 10/02/2008 have been fully considered but they are not persuasive.

11. The Applicant presents two definitions of the term "overlap". Under one definition, the prior art anticipates the invention, under the other definition, the prior art makes obvious the invention. Furthermore, from the drawings and specification, there is no evidence that the braided member does overlay the tubular member in the original invention. The relationship between the two members is broadly described as a junction (see 186 in figures 2a and 2b).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aarti Bhatia whose telephone number is (571) 270-5033. The examiner can normally be reached on Monday-Thursday 8:00am - 6:30pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

/Aarti Bhatia/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763